PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

	olicant 0401		gent's file reference	FOR FURTHER	ACTION	See Notificati Preliminary E	on of Transmittal of International xamination Report (Form PCT/IPEA/416)
PC	TÆS	2004	olication No. 000169	International filing da 16.04.2004		th/year)	Priority date (day/month/year) 16.04.2003
A61	1 L2/1	8	tent Classification (IPC) or bo				
1.	Thi	s inter		nination report has b	On proper	ed by this Inte	ernational Preliminary Examining
2.	This	REP	ORT consists of a total of	5 sheets, including	this cover	sheet.	
	×	This bee (see	s report is also accompani n amended and are the ba Rule 70.16 and Section	ied by ANNEXES, i.e asis for this report ar 607 of the Administr	e. sheets of nd/or sheets ative Instru	the descriptions containing rections under t	on, claims and/or drawings which have ectifications made before this Authority he PCT).
	The		nexes consist of a total of				
3.	This	repoi	t contains indications rela	ting to the following	items:		
	1	\boxtimes	Basis of the opinion				
	II		Priority				
	Ш		Non-establishment of op	inion with regard to	novelty, inv	entive step a	nd industrial applicability
	IV		Lack of unity of inventior	1	•		-a moderal applicability
	٧	☒	Reasoned statement und citations and explanation	der Rule 66.2(a)(ii) was supporting such s	/ith regard t	to novelty, inv	rentive step or industrial applicability;
	VI		Certain documents cited				
	VII		Certain defects in the inte	ernational application	n		
	VIII		Certain observations on	the international app	lication		
Date o	of subi	nissio	n of the demand		Date of co	mpletion of this	s report
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Name prelimi	and n	nailing	address of the international ing authority:		Authorized	Officer	
	<u>)</u>	Euro D-80 Tel.	ing authority: pean Patent Office p298 Munich +49 89 2399 - 0 Tx: 523656 6 +49 89 2399 - 4465	эрти d	Ladenbu Telephone	Irger, C No. +49 89 23	99-8276

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/ES2004/000169

 Basis of the repe 	ort	rep	the	of	Basis	I.
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1. With regard to the elements of the international application (Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)): Description, Pages 1-25 filed with the demand Claims, Numbers 1-24 received on 18.07.2005 with letter of 15.07.2005 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item. These elements were available or furnished to this Authority in the following language: English , which is: the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)). the language of publication of the international application (under Rule 48.3(b)). the language of a translation furnished for the purposes of international preliminary examination (under Ø Rule 55.2 and/or 55.3). 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing: contained in the international application in written form. filed together with the international application in computer readable form. furnished subsequently to this Authority in written form. furnished subsequently to this Authority in computer readable form. The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished. The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished. 4. The amendments have resulted in the cancellation of: the description, pages: the claims, Nos.: the drawings. sheets: This report has been established as if (some of) the amendments had not been made, since they have 5. been considered to go beyond the disclosure as filed (Rule 70.2(c)). (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this

Form PCT/IPEA/409 (January 2004)

6. Additional observations, if necessary:

INTERNATIONAL PRELIMINARY **EXAMINATION REPORT**

International application No.

PCT/ES2004/000169

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Yes: Claims

No: Claims

1-24

Inventive step (IS)

Yes: Claims

No: Claims

1-24

Industrial applicability (IA)

Yes: Claims Claims

1-24

No:

2. Citations and explanations

see separate sheet

V.2 Reasoned statement: Citations and explanations

1. Reference is made to the following documents cited in the search report:

D1= EP-A-0 775 439

D2= JP-A-6 321 711 (+ PAJ/JPO and WPI/DERWENT abstracts)

D3= JP-A-5 305 126 (+ PAJ/JPO and WPI/DERWENT abstracts)

The prior art documents D1-D3 (see e.g. D1, claim 1, col.1 l.7-10, Examples 7, 11-14; D2, PAJ abstract; D3, WPI abstract) already disclose the use of compositions comprising ≤ 20% of a (C1-C20) dialkyl ketone peroxide, e.g. methyl ethyl ketone peroxide (MEKP), as germicides and fungicides in sterilizing and disinfecting methods.

The subject-matter of the present application therefore is not new (Articles 33(1), 33(2) PCT).

Concerning the reply of 15.07.2005 to the written opinion dated 17.03.2005, applicant's attention is drawn to e.g. claims 3,8,14 of D1 (15-20%, 12-18%, 14%), and to the fact that current claim 1 does not exclude the presence of another active ingredient (see "a composition that **comprises** ...").

- 3. The application also calls for several remarks as concerns clarity (Article 6 PCT).
- 3.1 It is general knowledge that e.g. MEKP is a hazardous product, reacts violently with various organic and metallic materials, is explosive and a severe irritant for skin and mucous membranes. Thus, it is questionable whether MEKP can be used safely at dosages as high as 20%, especially if applied to the human or animal body (see e.g. 3 first lines of claim 18).

MEKP does not appear to be a non-toxic, non-ecotoxic product (see description p.1 l.7, p.4 l.21).

In the light of the passage p.6 I.32-33, that a sterilizing agent eliminates "all life forms", it is questionable how such agent can be used in human or animal therapy (see claim 18, first line).

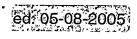
3.2 The term "isomer" used e.g. in claim 1 is unclear in the context of the invention. It is

EXAMINATION REPORT - SEPARATE SHEET

evident that not any structural isomers of the dialkyl ketone peroxides (e.g. the polyol HO-CH₂-CH(OH)-CH(OH)-CH₂-OH is also an isomer of MEKP) will exhibit biocidal properties.

The polymeric forms of a compound (see description p.8 l.12-26) are usually not covered by the term "isomer".

- 3.3 On p.8 l.2-5, it is stated that the alkyl groups can be unsaturated, substituted by diverse organic or inorganic groups. This statement renders the subject-matter of e.g. claim 1 unclear, since unsaturated or substituted groups are normally not covered by the sole term "alkyl".
- 3.4 The compositions used in claims 1 and 19 comprise a dialkyl ketone peroxide at a percentage by volume less than or equal to 20%. It is noted that such definition also includes very low percentages, close to zero, e.g. 0.1 ppm. It is doubtful that the composition is effective at such dosage of active compound.
- 3.5 Preferred embodiments (see in particular independent claims 1 and 19) should be claimed in separate, dependent claims.
- 3.6 The description must be brought into accord with the amended claims.



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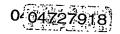
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CLAIMS

- 1. Use of a composition that comprises a (C1-C20) dialkyl ketone peroxide, or an isomer or a mixture of isomers of the same, preferably a (C1-C6) dialkyl ketone peroxide, or an isomer or a mixture of isomers of the same, at a percentage by volume less than or equal to 20%, as a biocide, sterilizing, antiseptic, disinfecting or anti-parasitic agent.
- 2. The use according to claim 1, characterised in that the composition comprises a (C1-C20) dialkyl ketone peroxide, or an isomer or a mixture of isomers of the same, preferably a (C1-C6) dialkyl ketone peroxide, or an isomer or a mixture of isomers of the same, in a percentage by volume less than or equal to 5%, preferably less than or equal to 0.3%.
- 3. The use according to anyone of previous claims, characterised in that said composition comprises methyl ethyl ketone peroxide, or an isomer or a mixture of isomers of the same.
- 4. The use according to anyone of previous claims, characterised in that said composition comprises water, or an adequate organic solvent or an oil as an excipient.
- 5. The use according to claim 4, characterised in that the organic solvent is an alcohol.
- 6. The use according to claim 5, characterised in that the alcohol is selected from: hexylene glycol, polyethylene glycol 200, propylene glycol and glycerin-formal, diacetone alcohol, ethanol, n-propanol or isopropanol
- 7. The use according to anyone of claims 1-6, as a bactericide.
- 8. The use according to anyone of claims 1-6, as a virucide.

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- 9. The use according to anyone of claims 1-6, as a fungicide.
- 10. The use according to anyone of claims 1-6, as a sporicide.
- 11. The use according to anyone of claims 1-6, as a mycobactericide.
 - 12. The use according to anyone of claims 1-6, as a protocide.
- 13. The use according to anyone of claims 1-6, as an algicide.
- 14. The use according to anyone of claims 1-6, as a prionicide.
- 15. The use according to anyone of claims 1-6, as an insecticide.
- 16. The use according to anyone of claims 1-6, as an arachnicide.
- 17. The use according to anyone of claims 1-6, as a miticide.
- 18. The use according to the previous claims, applied to human and animal therapy, human and animal hygiene, the washing and disinfection of healthy or damaged skin both in man and animals, packing, wrapping, medical and industrial instruments, sanitary surfaces and healthcare environments, premises, surfaces in general, industrial installations, refrigeration towers, air conditioning conduits, machinery and installations in the food industry, agriculture and fisheries installations, sanitary hot water circuits, purification of drinking water for human or animal consumption, or any other application: industrial, domestic, environmental, agricultural, forestry, urban, pharmaceutical, civil, military, police purposes, scientific, technological, spatial, geological, healthcare or health prevention.
- 19. Method of sterilisation, disinfection, asepsia or deparasitisation that comprises the application of a composition comprising a (C1-C20) dialkyl ketone peroxide, or an isomer or a mixture of isomers of the same, preferably a (C1-C6) dialkyl ketone peroxide, or an isomer or a mixture of isomers of the same, at a percentage by volume less than or equal to 20%.

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- 20. The method according to claim 19, characterised in that said composition comprises a (C1-C20) dialkyl ketone peroxide, or an isomer or a mixture of isomers of the same, preferably a (C1-C6) dialkyl ketone peroxide, or an isomer or a mixture of isomers of the same, at a percentage by volume less than or equal to 5%, preferably less than or equal to 0.3%.
- 21. The method according to claims 19-20, characterised in that said composition comprises methyl ethyl ketone peroxide, or an isomer or a mixture of isomers of the same.
- 22. The method according to claims 19-21, characterised in that said composition comprises water, an adequate organic solvent or an oil as an excipient.
- 23. The method according to claim 22, characterised in that the organic solvent is an alcohol.
- 24. The method according to claim 23, characterised in that the alcohol is selected from hexylene glycol, polyethylene glycol 200, propylene glycol and glycerin-formal, diacetone alcohol, ethanol, n-propanol or isopropanol.